EC-2000-007
IV-D-041

The Dow Chemical Company
Midland, Michigan 48674

2030 Dow Center

United States Environmental Protection Agency
Enforcement and Compliance Docket and Information Center (Mail Code 2201A)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Attention: Docket No. EC-2000-007

Dear Sir or Madam:

Attached are four copies of The Dow Chemical Company's presentation at the January 17, 2002 public hearing on CROMERRR's recordkeeping provisions. Please put them into the docket.

Sincerely,

Mark Duvall
Counsel

Attachments

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Midland, Michigan 48674

Public Hearing on
CROMERRR's Recordkeeping Provisions
Washington, DC
January 17, 2002

PRESENTATION OF THE DOW CHEMICAL COMPANY

Good morning. I am Mark Duvall, an attorney with the Legal Department of The Dow Chemical Company in Midland, Michigan. I am pleased to have the opportunity to offer Dow's comments on the recordkeeping provisions of EPA's proposed Cross-Media Electronic Reporting and Recordkeeping Rule, known as CROMERRR. Dow is a global manufacturer of chemicals and plastics with many facilities in the United States that are subject to EPA recordkeeping requirements.

EPA has requested comments on a number of questions related to the proposed recordkeeping provisions. Of these, the most important is "whether or not the recordkeeping provisions . . . should be withdrawn and addressed in a separate rulemaking." Before getting to the other questions, it is appropriate to answer this pivotal question. Dow's response is that the recordkeeping provisions should be withdrawn. In particular, Dow would like to make the following points:

- In proposing the recordkeeping provisions, EPA misunderstood the role of electronic recordkeeping in meeting EPA recordkeeping requirements. It assumed that little or none was going on; in fact, electronic recordkeeping is pervasive. In practical terms, electronic recordkeeping is not voluntary and regulated entities cannot choose to forego it. With CROMERRR, the entire regulated community would be subject to a mandatory, burdensome recordkeeping regulation.

- The cost of meeting the CROMERRR recordkeeping provisions would be well over $40 billion, making it the most expensive EPA regulation ever promulgated.
- EPA asserted that the recordkeeping provisions are needed to meet the Government Paperwork Elimination Act. This is incorrect. EPA needs to take no action in order to make electronic recordkeeping an option, because it has already done so. However, the CROMERRR recordkeeping provisions would be directly contrary to several key provisions of the GPEA. They would also violate the OMB guidance on implementation of the GPEA.
- EPA maintains that the recordkeeping provisions are needed for enforcement of EPA recordkeeping requirements in the electronic context. This, too, is incorrect, for several reasons.
    - EPA has done nothing to establish that there is a problem in need of fixing. The nature of many highly automated information collection processes today virtually precludes any opportunity for tampering with electronic records to occur in the first place. The recordkeeping provisions would do nothing to prevent fraud from occurring before an electronic record is created. There is nothing in the rulemaking record to indicate that fraud in electronic recordkeeping is widespread or that existing enforcement resources are incapable of policing electronic recordkeeping fraud. In the absence of such evidence, the recordkeeping provisions are arbitrary and capricious.
    - It is by now well established that electronic records are generally admissible in court. To the extent that admissibility was a problem in the past, the GPEA significantly reduced that problem.

- The final justification offered for the recordkeeping provisions is the need to tie electronic records to individuals responsible for those records. Ironically, the CROMERRR recordkeeping provisions could backfire against prosecutors by raising the bar in non-environmental cases for establishing the reliability of electronic records or for proving fraud. In any case, this objective cannot justify the enormous burdens posed by the recordkeeping provisions.

- EPA should sever the recordkeeping provisions from the rest of CROMERRR, as they need to be thoroughly reconsidered. Failure to sever could mean that the electronic recordkeeping and electronic signature provisions would not be promulgated in time to meet the GPEA deadline. It could also lead to their invalidation on judicial review as a court would preclude the recordkeeping provisions from taking effect.
- Finally, our responses to the other questions posed by EPA are presented.

DISCUSSION

1. The Assumptions Underlying the Recordkeeping Provisions Are Incorrect.

In drafting the recordkeeping provisions, EPA assumed that its recordkeeping requirements were currently being met primarily through paper records, and that electronic recordkeeping was an emerging phenomenon which could be influenced. These are both incorrect. As a consequence, today electronic recordkeeping is not voluntary in any meaningful sense. Rather, it is indispensable for complying with EPA recordkeeping requirements.

EPA assumed that only 428 facilities per year would become subject to the CROMERRR recordkeeping provisions, because those 428 facilities would be in a

position to choose to adapt their electronic recordkeeping systems to meet the demands of CROMERRR. EPA assumed that all other facilities would be in a position either to abandon electronic recordkeeping, or not to initiate it.

As is now apparent, virtually all EPA-regulated facilities use electronic records to meet EPA recordkeeping requirements. For many of those recordkeeping requirements, it is literally impossible to comply without creating electronic records. For others, electronic recordkeeping is far more efficient than exclusively paper recordkeeping. Regulated entities have invested many billions of dollars in computer systems which in part serve to meet EPA recordkeeping requirements. Almost none of them would meet the CROMERRR design criteria of having an audit trail and capacity to transfer records electronically across multiple generations of hardware and software without data loss. Thus, with CROMERRR each facility subject to EPA recordkeeping requirements would face a mandatory rule imposing severe technical and financial burdens. There would be nothing voluntary about the recordkeeping provisions.

The number of such facilities is uncertain, but it is certainly over a million. In 1999, Fred Stiehl, then the Director of OECA's Enforcement Planning, Targeting and Data Division, stated that EPA regulates approximately six million facilities (1.25 million in its core programs). EPA's FY 2000 GPRA Performance Report stated:

> In partnership with the states and federally recognized tribes, EPA's enforcement and compliance assurance program regulates approximately 8 million entities that range from community drinking water systems to pesticide users to major industrial facilities. Compliance data are maintained for approximately 1.7 million of these entities. These include municipal sewage treatment plants, large manufacturing and industrial operations, and hazardous waste treatment and storage facilities. The remaining 6.5 million entities range from small business facilities to individual property owners.

In this docket EPA has estimated that 1.2 million facilities submit reports to EPA. Even as low a number as 1.2 million facilities shows that the use of electronic recordkeeping to meet EPA recordkeeping requirements is pervasive. What might have been tolerable with 428 facilities per year at the dawn of electronic recordkeeping is unacceptable for over a million facilities already deeply involved with electronic recordkeeping.

As a result, the CROMERRR recordkeeping provisions do not reflect the reality that electronic recordkeeping has been and is now the norm throughout the regulated community. Any effort to force major changes to the nature of electronic recordkeeping would be very disruptive and expensive.

2. The CROMERRR Recordkeeping Provisions Would Be the Most Expensive EPA Requirements in History.

Using EPA's own estimates, a "low-end" electronic recordkeeping system would cost $40,000 ($25,000 for the system, $15,000 for additional set-up and training). EPA estimated that the cost of maintaining the system and managing the records would be $17,000 annually. If only 1.2 million facilities would incur those costs, the initial cost of meeting the CROMERRR recordkeeping provisions would be $48 billion, and the annual maintenance cost would be $20 billion.

In contrast, OSHA's ergonomics rule would have affected 6.1 million facilities and would have cost $4.5 billion annually. Using EPA's own estimates, just the initial cost of meeting the CROMERRR recordkeeping provisions would be more than ten times the annual cost of the ergonomics rule. The annual cost for maintaining a system meeting CROMERRR recordkeeping requirements would be more than four times the annual cost of the ergonomics rule. Congress passed legislation disapproving the ergonomics rule, Public Law 107-5. In signing that legislation less than a year ago, President Bush stated:

> There needs to be a balance between and an understanding of the costs and benefits associated with Federal regulations. In this instance, though, in exchange for uncertain benefits, the ergonomics rule would have cost both large and small employers billions of dollars and presented employers with overwhelming compliance challenges. Also, the rule would have applied a bureaucratic one-size-fits-all solution to a broad range of employers and workers—not good government at work.

These comments are even more applicable to the CROMERRR recordkeeping provisions than they are to the ergonomics rule.

It is not appropriate to rely on the EPA cost estimates, as they are much too low. The $40,000 initial cost and $17,000 annual cost were just for a "low-end" system. While the details of what a "low-end" system entails are not included in the public docket, it is clear that such a system will not suffice to meet EPA recordkeeping requirements in today's complex, highly automated environment.

At a previous public meeting on CROMERRR, Dow submitted an estimate that the actual cost of meeting the CROMERRR recordkeeping provisions would exceed $1,000,000 per facility. But there is no need to speculate as to the costs, because we have available a real-world example of the costs of compliance with FDA's own electronic reporting and recordkeeping rule, 21 CFR Part 11. EPA acknowledges that it based the CROMERRR requirements on those of Part 11. A white paper issued just last year on implementation of Part 11 reported:

> In a recent survey conducted by Accenture concerning leading companies' approaches to Part 11 compliance, respondents place the total cost to become compliant with Part 11 at about $100+ million, with additional time and money slated for maintenance.
>
> Given the necessity to invest such a large amount of resources, both initially and on an ongoing basis, this regulation has a greater direct financial impact than many other regulations for pharmaceutical and medical device companies.

Thus, for some companies CROMERRR costs can be expected to reach $100 million per company or more. The $40,000 initial and $17,000 annual costs suggested by EPA are unrealistic.

The CROMERRR recordkeeping costs would total in the tens to hundreds of billions of dollars. This is more expensive than the Clean Air Act program. These costs would make what is essentially a paperwork requirement arbitrary and capricious.

3. The CROMERRR Recordkeeping Provisions Are Not Needed to Meet the GPEA.

With costs of such a magnitude contemplated for the recordkeeping provisions, we should ask why EPA considered the provisions necessary. The preamble reports that "EPA is proposing [CROMERRR], in part, under the authority of the Government Paperwork Elimination Act, Public Law 105-277". The recordkeeping provisions are not needed to meet EPA's obligations under the GPEA. They would in fact be contrary to the purposes of the GPEA by treating electronic records less favorably than paper records.

The GPEA directs OMB to ensure that by October 2003 Executive agencies provide "for the option of the electronic maintenance, submission, or disclosure of information, when practicable as a substitute for paper", and "for the use and acceptance of electronic signatures, where practicable." Thus, the GPEA is mainly an electronic reporting and electronic signatures statute. It does mention "the electronic maintenance" of records, but that is not its chief focus.

The only recordkeeping aspect of the GPEA is that agencies provide "for the option of the electronic maintenance" of information. EPA does not need to take any action to provide that option; it already exists. In a previous submission to this docket,

Dow provided a list of 36 Clean Air Act regulations that already explicitly allow electronic recordkeeping. Most other EPA recordkeeping requirements are entirely media-neutral as to how the records must be created or maintained, and thus implicitly allow electronic recordkeeping.

Ironically, the recordkeeping provisions would actually run counter to the express purposes of the GPEA. The GPEA amended the Paperwork Elimination Act, whose primary purpose is to "minimize the paperwork burden for individuals, small businesses, . . . and other persons resulting from the collection of information by or for the Federal Government". Instead of minimizing paperwork burden, the CROMERRR recordkeeping provisions would add tens to hundreds of billions of dollars of additional paperwork costs.

Furthermore, the legislative history of the GPEA indicates Congress' belief "that the bill will not subject any individual or businesses affected by the bill to any additional regulation." Clearly, with electronic recordkeeping already indispensable to meeting EPA recordkeeping requirements, CROMERRR would subject over a million facilities to new and very burdensome regulation.

The legislative history also indicates that GPEA provisions should have a net positive benefit for the regulated community:

> After full implementation of the bill, individuals and businesses will benefit from the potential cost savings by having the opportunity to conduct transactions electronically with the Federal government.

EPA has already determined that the recordkeeping provisions will have a net negative benefit for the regulated community. The preamble says:

> Therefore, our estimates indicate that . . . facilities may not find it cost-effective to develop an electronic records system unless it addresses both EPA and non-EPA business purposes.

Its own cost-benefit analysis concludes that even the underestimate of $40,000 to acquire a compliant recordkeeping system "is prohibitive for solely preserving environmental compliance reports." The main purpose of the GPEA is to benefit the regulated community, not EPA enforcers. Yet the CROMERRR recordkeeping provisions would only hurt the regulated community, contrary to the purposes of the GPEA.

The legislative history emphasizes that the GPEA "is intended to preclude agencies or courts from systematically treating electronic documents and signatures less favorably than their paper counterparts." Yet that is exactly what EPA does with the CROMERRR recordkeeping provisions. The preamble reports that one purpose of the recordkeeping provisions is to "improve the level of corporate and individual responsibility and accountability for electronic reports and records that currently exists in the paper environment." CROMERRR systematically disfavors electronic records by imposing substantial anti-fraud provisions, such as audit trail requirements, that are not applicable to paper counterparts. Paper documents may be discarded after conversion to microfiche or other format without penalty, whereas CROMERRR would prohibit discarding electronic records even if converted to other formats, solely because the electronic meta-data would not be captured. These and other CROMERRR requirements discriminate against electronic records, in direct contradiction of the purposes of the GPEA.

OMB recognized that agencies would be tempted to impose anti-fraud provisions in implementing the GPEA, and it warned against the kind of excessive zeal found in CROMERRR:

> Setting up a very secure, but expensive, automated system may in fact buy only a marginal benefit of deterrence or risk reduction over other alternatives and may not be worth the extra cost. For example, past experience with fraud risks, and a careful analysis of those risks, shows that exposure is often low. If this is the case a less expensive system that substantially deters fraud is warranted, and not an absolutely secure system.

CROMERRR calls for an absolutely secure electronic system. It also prescribes a single set of requirements for all EPA-mandated recordkeeping, regardless of the risk of fraud. OMB specifically cautioned against this "one-size-fits-all" approach:

> Agencies should also keep in mind that GPEA specifically states that electronic records and their related electronic signatures are not to be denied legal effect, validity, or enforceability merely because they are in electronic form. We are not, therefore, prescribing "one size fits all" requirements applicable to transactions regardless of their sensitivity.

Thus, the CROMERRR recordkeeping provisions would violate both the GPEA itself and OMB's guidance on implementing the GPEA.

4. EPA Has Not Justified Its Claimed Need to Have the Recordkeeping Provisions Deter or Detect Fraud in Electronic Recordkeeping.

While it is relevant to the provisions on electronic reporting and electronic signatures, the GPEA is simply not a reason for EPA to adopt the CROMERRR recordkeeping provisions. EPA's real reason for proposing them is to prevent and detect fraud. The preamble admits:

> Among other things, today's proposal is intended to ensure that . . . fraudulent electronic submissions or record-keeping can be prosecuted to the full extent of the law.

EPA has not shown that the CROMERRR recordkeeping provisions are necessary to achieve this goal, or that any incremental enforcement benefits justify the cost and burdens of the recordkeeping provisions.

a. <u>EPA Has Not Shown That a Problem Exists That Needs to be Fixed.</u>

There is nothing in the rulemaking docket to indicate either that fraud in electronic recordkeeping is widespread, or even significant, or that existing enforcement resources are inadequate to deter and detect fraud.

It should be pointed out that for many highly automated processes common in EPA-regulated facilities, it is virtually impossible for any individual to commit fraud once an electronic instrument records data. An attempt to do so would leave evidence even in the absence of an audit trail. In that sense, electronic recordkeeping actually deters fraud.

Moreover, EPA has shown a great deal of success in detecting and punishing fraud in the few areas where it has been found to occur, particularly in environmental analytical laboratories. The EPA Inspector General recently stated in an open letter:

> In a continuing effort to deter these practices, the EPA-OIG is working closely with EPA's Criminal Investigations Division, other federal investigative organizations, and the Department of Justice to investigate and, as appropriate, prosecute all allegations of laboratory fraud. These efforts to date have resulted in substantial fines, penalties, incarcerations, federal suspension and debarment actions, and laboratory closures.

Thus, EPA has had success in detecting and punishing laboratory fraud without having the CROMERRR recordkeeping provisions.

There is nothing in the docket to indicate that CROMERRR would deter or detect the kind of fraud that does occur. If fraud were to consist of the manipulation of samples prior to analysis by electronic instruments, for example, CROMERRR would do nothing

to detect such fraud. It is the concept of "garbage in, garbage out"; an electronic record may faithfully preserve data that was manipulated prior to being recorded.

To the extent that fraud in laboratory electronic records is a problem at all, EPA already has provisions in place to fix the problem. EPA standard methods contain quality checks. The Good Laboratory Practice regulations contain what is, in effect, an audit trail requirement for automated data collection systems. If more is needed in the laboratory context, EPA has shown that it can address laboratory fraud issues without applying requirements to all EPA recordkeeping requirements.

There is nothing outside the laboratory area to suggest that fraud is a particular problem or that existing regulations are inadequate to deter and detect it. Thus, EPA has failed to justify the recordkeeping provisions.

b. Electronic Records Are Generally Admissible.

A phantom issue may be that the recordkeeping provisions are needed to assure admissibility of electronic records. Electronic records (or printouts thereof) have been held admissible for decades in both civil and criminal cases. Indeed, the Federal Rules of Evidence specifically facilitate the admission of electronic records by providing in Rule 1001(4) that the "original record" requirement for electronic records may be met by a printout shown to reflect the data accurately. The "business record" exception to the hearsay rule, Rule 803(6), typically operates to overcome hearsay objections by including "data compilation, in any form" among the kinds of regularly maintained business records accepted as an exception to the hearsay rule. The American Bar Association's Committee on the Law of Commerce in Cyberspace has reached the conclusion that the

Federal Rules of Evidence "are generally hospitable to the admission of electronic evidence", but should receive "fine tuning".

Any residual evidentiary concerns are reduced by the GPEA itself. It declares unambiguously:

> Electronic records . . . maintained in accordance with procedures developed under this title . . . shall not be denied legal effect, validity, or enforceability because such records are in electronic form.

Thus, courts may not discriminate against electronic records just because they are electronic.

c. Proving Individual Accountability.

From a prosecutor's perspective, the key requirement is that of proving that a particular individual improperly tampered with electronic records. Prosecutors in an electronic fraud case would have to describe how the fraud was accomplished and by whom, which could be a burden on them. That burden is no different than in any other fraud case, however.

Even assuming that CROMERRR would tend to deter fraud and facilitate fraud prosecutions, there is nothing in the rulemaking record to indicate that the incremental benefit from these results would outweigh the costs and burdens of the recordkeeping provisions. EPA seems to take the position that because they might be useful as an enforcement tool, they are worth any cost to the regulated community. As President Bush said in signing the legislation invalidating the ergonomics rule, there must be an understanding and balancing of the costs and benefits of regulatory action. In their absence, regulatory action is arbitrary and capricious.

In addition, it should be recognized that reducing EPA's burden in its enforcement cases carries with it a considerable danger to enforcers in other kinds of civil and criminal cases. Electronic records figure routinely in many kinds of cases, not just environmental. If CROMERRR-type assurances of reliability should become the standard against which courts measure proof of authenticity of electronic records, then other kinds of electronic records, lacking those assurances, may well be found to be unreliable. In other words, CROMERRR could raise the bar on what is needed to establish the reliability of electronic records. Similarly, if CROMERRR-type evidence of fraud becomes the standard for determining fraud in all cases involving electronic records, prosecutors may lose fraud cases that today they would win.

CONCLUSION AS TO WHETHER THE RECORDKEEPING PROVISIONS SHOULD BE WITHDRAWN

In summary, yes, EPA should withdraw the recordkeeping provisions. In light of the mistaken assumptions underlying them, their costs, their technical challenges, and the lack of need for adopting them in the first place, they should be withdrawn.

If not withdrawn, then on judicial review they would be held to be arbitrary and capricious. Such a finding might well extend to the electronic reporting and electronic signature provisions also. If EPA is interested in saving those provisions, which actually are needed to meet GPEA requirements, it should sever the recordkeeping provisions which could otherwise drag them down.

OTHER EPA QUESTIONS

1. What kinds of records do companies currently keep electronically to satisfy EPA regulatory requirements?

The vast majority of records Dow keeps to satisfy EPA recordkeeping requirements are generated electronically. EPA has hundreds of recordkeeping requirements, Dow is subject to many of them, and it uses electronic records in the process to meet most or all of them. Here are a few examples.

For Clean Air Act requirements, attached is a table of examples of electronic records kept at one Dow facility. Note, for example, that at this single facility Dow keeps daily emissions calculations for some 2,000 tanks and monthly fugitive monitoring records for some 100,000 valves and pumps. It records over a million data points annually. These data cannot even be collected other than electronically, much less maintained and compiled. Dow clearly has no choice on whether to keep electronic records for these Clean Air Act recordkeeping requirements; it is impossible to keep them except electronically.

Under the Clean Water Act, the outfall continuous water monitoring data (pH, temperature, and flow) for sites is kept electronically. For example, at one facility data is transmitted wirelessly from remote stations to a host PC, and then transmitted to other computer systems for trending. The other systems integrate the flows, select the needed high and/or low pH and temperature readings, and transmit these data to the laboratory information management system. At the end of the month, the laboratory information management system generates the data needed for the discharge monitoring report.

Dow uses electronic recordkeeping in conducting hundreds of toxicology, ecotoxicology, and environmental chemistry studies annually. For example, mammalian

toxicity studies under Good Laboratory Practices use electronic instruments which create electronic records. The kinds of data recorded include dosing information, body weights, food weights, histopathology data, and statistical calculations on all data. Other types of data recorded include animal room environmental data (temperature and humidity). Study types include acute, subchronic, chronic, oncogenicity, neurotoxicity, and other types of toxicology studies. Similarly, in its ecotoxicology studies conducted under GLPs, Dow records electronically such data as dosing information, temperature, pH, dissolved oxygen data, growth observations, and statistical analyses of this information. For GLP environmental chemistry studies, Dow records electronically data from biodegradation, respirometer, and other types of studies.

2. How prevalent is this electronic recordkeeping, and what kinds of systems are used?

At Dow, electronic recordkeeping is pervasive. Many kinds of systems are used.

In manufacturing, continuous, hourly, and daily records are kept electronically just because of the sheer volume of records that would otherwise have to be filed and maintained. Monthly data is often a summation of more frequent data collection such as tank throughputs or turnovers, runtime meters, and shipment weigh tickets. The source data is collected by process computers and is stored or transferred to other computer systems for storage until the summation of the data is performed on a monthly or (sometimes) an annual basis. This data is then used for emissions calculations (done either by the process computer or by some other software being run in a different environment).

Dow's agricultural chemicals subsidiary uses some 180 different systems to collect electronic data for laboratory and field studies. They capture massive amounts of data. In most or all cases, these systems would not meet CROMERRR requirements.

R&D has a diverse computing architecture that comprises instruments, automation, networks, workstations, and the like. Often the electronic recordkeeping is in a form provided by the instrument vendor. One of the challenges we face is extracting electronic data out of these often proprietary systems to be reused in other applications. We have practically every commercially released system (e.g., Microsoft DOS®, Windows® 3.x, Windows® 9x, Windows® 2000, Windows® NT, Unix®, etc.), and some systems developed in-house.

As for laboratory instrumentation, we have practically every make and model of analytical instruments. With some 5,000 researchers globally, we estimate that Dow probably averages two instruments per researcher, for a total of about 10,000, and approximately 6,000 PCs connected to these instruments. Again, the diversity of instruments, PCs, software, and configurations is overwhelming. Most of the instruments do not meet CROMERRR recordkeeping requirements. For example, many lack an audit trail capability, and there is no long-term archiving of the electronic data on the instrument due to storage inadequacy and other technical considerations.

3. How are automatically captured data and other raw data maintained electronically?

As a general matter at Dow, it is up to the individual instrument owner or business function to determine the business and regulatory need and consequently the appropriate method for data capture and retention. Dow provides a variety of hardware and software tools, including file servers, PCs, databases, etc. Based on need rather than "one-size-

fits-all" standards, this culture creates a diversity of solutions. Some people may choose to move their electronic data to paper format, others may store it on a local hard drive, some may store it on network servers, while still others may store data in vendor-provided proprietary software. Dow often uses LIMS to store intermediate results and reports, but raw data may not be stored there due to the sheer volume of raw data or lack of tools that can store and retrieve raw data using that system.

4. How will the proposed rule affect companies' electronic recordkeeping practices, and do some of the proposed provisions raise more issues than others?

The proposed rule would require a complete inventory and evaluation of each instrument, electronic device, and software package to determine the electronic and computational capability to gather, store, retrieve, and audit electronic records in a manner prescribed by the proposed rule. In almost all cases, some modifications to the electronic device, procedures (work processes), network, infrastructure (user authentication), etc., would be required. In cases where modification would not be possible (due to age, lack of vendor support, etc.), then new equipment and software would need to be purchased. We estimate that this would require an effort on the same scale as preparing for Y2K, involving millions of dollars, large teams of IT professionals, and many man-years of time.

These tasks would require large time commitments, probably mostly from consultants, because Dow does not have the necessary human resources readily available.

The two most troublesome provisions of the proposed rule would be the audit trail requirement and the obligation to maintain electronic records for the entire record retention requirement.

Many electronic instruments, software, or processes lack an audit trail capability. For example, like many companies, Dow often uses Microsoft Excel® for collection of data, but Excel lacks an audit trail capability. Microsoft has indicated no interest in adding one to the software. Dow is aware of only one vendor purporting to have software that would add an audit capability to Excel. The vendor plans to charge a hefty fee for use of the software. Its utility is unknown to Dow.

Aside from the software costs, the proposed audit trail requirement would impose very large costs due to the memory required to maintain the meta-data collected through the audit trail. Most software is written to minimize the amount of memory used by the application; the proposed audit trail requirement would multiply the system memory requirements by a substantial factor.

Another major problem would be the proposed requirement to maintain electronic records in electronic format for the entire retention period, discussed in Question 6 below.

5. How do companies currently ensure the integrity and reliability of their electronic records, especially where they do not use audit trails, and what role do recognized industry standards play?

Dow has extensive internal Information Security provisions to ensure against tampering with electronic records. These include the use of passwords, limiting access to the maintenance of electronic systems to authorized persons, user training, and other means.

In many situations, Dow validates systems to ensure that they are operating properly. It is the responsibility of the organization within Dow determine what level of validation, if any, is needed.

We note that only two years ago the Government Accounting Office questioned the adequacy of EPA's own systems to ensure the integrity and reliability of its electronic records. In a February 2000 report entitled "Information Security: Fundamental Weaknesses Place EPA Data and Operations at Risk", the GAO concluded:

> Overall, our review found serious and pervasive problems that essentially render EPA's agencywide information security program ineffective. Current security program planning and management is largely a paper exercise that has done little to substantively identify, evaluate, and mitigate risks to the agency's data and systems. Moreover, our tests of computer-based controls have concluded that the computer operating systems and the agencywide computer network that support most of EPA's mission-related and financial operations are riddled with security weaknesses . . . . EPA's computer systems and the operations that rely on these systems are highly vulnerable to tampering, disruption, and misuse. Moreover, EPA cannot ensure the protection of sensitive business and financial data maintained on its larger computer systems or supported by its agencywide network.

There is some irony in EPA using CROMERRR to dictate to the regulated community how it should ensure the reliability of electronic records when EPA's own practices are subject to such strong criticism by the GAO.

6. What special issues are raised by proposed criteria for long-term archiving, and how do companies currently address this problem?

Long-term archiving in electronic format allows only two options as hardware and software change over time during the retention period: (1) maintain legacy systems, and/or (2) migrate data to successive generations of hardware and software. As the Justice Department has advised government agencies:

> computer technology is rapidly changing and software and formatting standards may quickly become obsolete. Computer-stored data may become useless unless the agency can provide the continued capability or can accurately translate the document as more modern systems are implemented.

Maintaining legacy systems is tremendously expensive and often ultimately unsuccessful. Accordingly, data migration is a practical necessity. Given some very long

record retention requirements, data may need to be migrated several times over its lifetime. Migrating data involves potential loss or corruption of data and often decreased utility of the data. As a result, Dow does not support long-term archiving in electronic format.

Dow has always achieved long-term archiving by either moving data to paper or to some other eye-readable format, such as microfilm. Computing technology has never provided long-term archiving due to the constant changing of operating systems, applications, file formats, etc. Dow's Electronic Records Policy provides that if the "shelf life" of a storage medium is not long enough to handle the full retention schedule of a record, provision must be made to transfer the record before it becomes unusable. Similarly, if technology is about to become outdated (so Dow will not have the ability to read records stored on that medium), provision must be made to assure continued access to the records.

Interestingly, EPA has always allowed exact copies of raw data from GLP studies to be stored in lieu of the original raw data. Back in 1980, EPA said, "Obviously, microfilming of [GLP data] is often appropriate at some point to reduce the bulk of such data . . . ." In 1989 EPA even added a provision to the GLP regulations, 40 C.F.R. §§ 160.195(i), 792.195(i), explicitly stating that GLP records may be retained either as originals or as true copies. Thus, for GLP studies, it is common practice to convert electronic records to paper or other format when necessary for archiving purposes.

It is instructive to see what problems federal agencies have encountered with respect to long-term archiving of electronic records. A recent survey of 150 federal agencies conducted on behalf of the National Archives and Records Administration

found that the government is strongly oriented toward retaining electronic documents only as paper printouts:

> Technology tools for managing electronic records do not exist in most agencies. The agency information technology environments have not been designed to facilitate the retention and retrieval of electronic records. Despite the growth of electronic media, agency record systems are predominately in paper format rather than electronic. Virtually every agency visited indicated that the official policy is that their records will be maintained in paper format. Yet the agencies recognize that most records are now created in an electronic environment—in word processing documents, spreadsheets, databases, and the like. The predominant e-mail policy is to print out e-mails that are considered records and to save the paper copies. The chief paradox of today's Federal RM [records management] is the disconnect between paper and electronic recordkeeping.

Thus, the federal government itself has yet to come to terms with long-term archiving. NARA advises that long-term archiving "presents special challenges, such as maintaining the record when migrating from one system to another."

An EPA document in the rulemaking docket (II-A-038) refers to "the lack of a government or industry standard for archiving digitally signed data". It advises that:

> The long-term archiving of electronic data in a paper format is an option that will appeal to many small and medium sized organizations . . . . While it may seem counter-intuitive to convert electronic records to paper for archiving, paper is a format that is very stable, has a long shelf life, and requires minimal technological expertise to deal with.

In other words, EPA joins with industry and other government agencies in recognizing that a viable long-term solution to archiving electronic records is paper retention.

7. Where archiving involves the conversion of electronic records to paper, how do companies assure data integrity and reliability, and what role do recognized industry standards play?

Dow has a Records Management program in place that describes how to manage records, in both electronic and paper formats. Employees are trained and reminded on an annual basis to label and classify documents, review them for potential retention or deletion, and the like. Processes are in place for technical reviews, audits, etc.

GLP studies are all inspected before they are archived. Each study report includes a quality assurance statement by the organizational QA staff and a compliance statement signed by the study director.

8. Are there new products or technologies that will help companies address the proposed standards for electronic recordkeeping?

Currently, there are no proven "off the shelf" solutions that purport to address all the CROMERRR recordkeeping provisions. There are products and technologies that are emerging that claim to address some of the proposed standards. There are also some products that claim to address the FDA's 21 CFR Part 11 requirements. Some would be stand-alone products capable of integrating into a system, while others would be add-ons for existing systems. An example is Scientific Data Management Systems, along with enhancements to Dow's current systems such as LIMS and possible add-ons. These products need to be evaluated to determine if the claims are indeed true and identify where they fall short of meeting CROMERRR and user requirements. Full system validation is a costly and time-consuming effort.

ATTACHMENT

Examples of electronic records kept by one Dow facility to meet Clean Air Act recordkeeping requirements.

Type of Data	Kept Electronically?	Data Reduction or Calculations Done Electronically	Data or Reduced Data Submitted in Federal Reports?	Report Submitted Electronically?	Frequency of Data Collection	Frequency of Data Reduction or Calculation	Frequency of Report	Number at Facility (estimated)
Flare Pilot Monitors	Y	Y	Y		Continuous[1]	Daily	Semiannual	4
Opacity Monitors	Y	Y	Y		Continuous[1]	Daily	Semiannual	0
Temperatures	Y	Y	Y		Continuous[1]	Daily	Semiannual	6
Flow Indicators	Y	Y	Y		Continuous[1]	Daily	Semiannual	~30
Fugitive Monitoring	Y	Y	Y	Y[4]	M/Q/S/A	Annual	S/A	~100,000 Valves and Pumps
Process Analyzer Output	Y	Y	Y		Hourly	Daily	Annual	~4
Area Monitoring[2]	Y	Y			Negotiated			15
Training Records[3]	Y				Biennial			2
Notifications/Reports[3]	Y		Y		Annual		Annual	18
CEMS	Y	Y	Y		Hourly	Daily	Semiannual	26
PEMS	Y	Y	Y		Continuous[1]	Daily	Semiannual	1
Performance Tests	Y	Y	Y		Q/S/A	Q/S/A	Q/S/A	~5 per year
Emission Calculations[4]								
– Tank Throughputs	Y	Y	Y	Y	Daily	Monthly	Annual	~2000 Tanks
– Loading Throughputs	Y	Y	Y	Y	Daily	Monthly	Annual	~15 Loading Racks
– Flowmeters	Y	Y	Y	Y	Daily	Monthly	Annual	~50
– Run Meters	Y	Y	Y	Y	Hourly	Monthly	Annual	~8
– Analytical Data	Y	Y	Y	Y	As Needed	Monthly	Annual	~30
– Manifest Data (weight tickets)	Y	Y	Y	Y	As Needed	Monthly	Annual	Unknown
TOC	Y	Y	Y		Continuous	Daily	Monthly[5]	~3
pH	Y	Y	Y		Continuous	Daily	Monthly[5]	~4

Total number of data points per year exceeds 1,000,000.

[1] Defined as a record every 15 seconds.
[2] Vinyl Chloride NESHAP (40 CFR 61)
[3] Asbestos NESHAP (40 CFR 61), HON Semiannual Reports, NSPS Semiannual Reports
[4] Example is TRI Report
[5] Discharge Monitoring Report – Reduced Monthly to Maximum, Minimum, Average